510(k) Summary

1. Date of Summary

MAY - 5 2009

April 14, 2009

2. 510(k) Applicant

Broncus Technologies, Inc.
1400 N. Shoreline Blvd., Bldg. A, Suite 8
Mountain View, California 94043
Phone: (650) 428-1600
FAX: (650) 428-1542

Contact Person: Mahtab Fatemi
Phone: (650) 428-1600
Fax: (650) 428-1542
e-mail: mfatemi@broncus.com

3. Device Overview

Trade Name: LungPoint™ Virtual Bronchoscopic Navigation (VBN) Software

Common Name: Picture Archiving and Communications Systems

Classification Name: System, Image Processing, Radiological
21 CFR 892.2050
Product Code LLZ

4. Predicate Device

The predicate device identified for the LungPoint VBN is as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint™ Virtual Bronchoscopic Navigation (VBN) System	Broncus Technologies, Inc	K090095, cleared to market on March 13, 09

5. Device Description

This premarket notification covers Broncus' LungPoint VBN System. The VBN System is a software only device, providing a navigation system to help the bronchoscopist plan and proceed to a predefined target site (also referred to as region of interest (ROI)) in the tracheobronchial tree. Specifically, the VBN system provides guidance to targets preselected by the bronchoscopist in lung tissue. In doing so, the VBN can provide guidance to lymph nodes to enable tissue sampling. It can also facilitate the return to an exact location in the lungs that had previously been treated for assessment of or continued therapy, or enable marker placement.

The VBN software is installed on an off-the-shelf PC computer system, and is intended to be used with commercially-available flexible bronchoscopes with CT scans that are saved in DICOM format.

6. Intended Use

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

7. Comparison to Predicate Device

The LungPoint VBN software has been modified to add an enhanced graphical user interface (GUI). The planning software has been simplified to streamline the planning process. 3-D visualization, improved pathway planning with airway labeling and a summary page have also been added. The procedure software has been enhanced to simplify the user interactions and provide user-friendly virtual bronchoscopy guidance with airway labeling and obstacles visualizations. As with the planning software, a new procedure summary page has also been added.

In addition to the changes to the GUI, the software now supports saving the procedure plans on the procedure/navigation computer instead of only on removable media. The operating system has also been updated to Windows Vista Business Edition from Windows XP Professional.

The User's Manual was updated to reflect the software modifications.

The VBN software has the same intended use, technological characteristics and hardware as the predicate.

8. Performance Data

The planned modifications were subjected to the Broncus design control process. Appropriate labeling changes, risk analysis, and design verification were performed to assure that the VBN software continues to meet its intended use.

9. Safety and Effectiveness

The VBN labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the software. Risk management is ensured via a hazard analysis and FMECA, which are used to identify potential hazards. These potential hazards are controlled via software development, verification testing and/or validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2009

Broncus Technologies, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091160
Trade/Device Name: LungPoint™ Virtual Bronchoscopic Navigation (VBN) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 20, 2009
Received: April 21, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

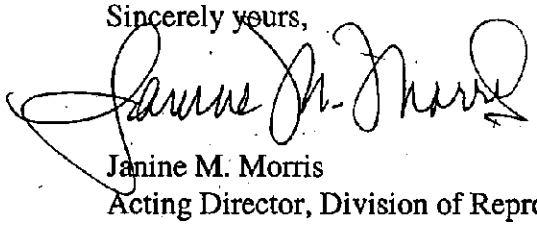
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 091160

Device Name: LungPoint™ Virtual Bronchoscopic Navigation (VBN) Software

Indications for Use: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-CounterUse _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Carolyn Y Neuland for J.M. Morris

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091160

Concurrence of CDRH, Office of Device Evaluation (ODE)